REMARKS/ARGUMENTS

Claims 75, 77, 84-89 and 91 are pending. By way of the present amendment, one (1) claim has been amended. Applicant respectfully submits that no new matter has been added by way of this amendment. Illustrative support in the specification can be found at least at page 35:2-4, 35:14-20 and page 44:30-31.

I. THE REJECTION UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN.

The office action dated November 10, 2011 rejected claims 75, 77, 84-89 and 91 under 35 U.S.C. § 103(a) as being unpatentable over US 5,447,918 ("McCullough") in view of Carroll, EP 584,588 ("Nomura"), US 6,268,385 ("Whittle") and the alleged "applicant's admission."

Applicant respectfully traverses this rejection, since no *prima facie* case of obviousness has been made. No combination of the references cited disclose every feature of the pending amended claims. Moreover, the references fail to teach the claimed limitation "wherein the pharmaceutical composition has low friability and a rapid disintegration time." Not only has the *prima facie* case not been established, but also the prior art lacks any apparent reason to combine the teachings of the cited references in the manner suggest by the examiner nor a reasonable expectation of success thereof.

The pending claims all require a tablet dosage form comprising about 10 to about 40 mg of a non-enteric coated omeprazole or a salt thereof; a buffering agent comprising about 1 mEq to about 20 mEq of sodium bicarbonate; and a disintegrant, wherein the pharmaceutical composition has low friability and a rapid disintegration time. The prior art is missing several of these limitations. Contrary to the Office Action's assertions, the prior art does not disclose a tablet dosage form containing omeprazole and sodium bicarbonate in the claimed ranges. None of the ranges cited by the Office Action disclose a tablet comprising sodium bicarbonate in an amount of about 1 mEq to about 20 mEq in conjunction with about 10 to about 40 mg of a non-enteric coated omeprazole. Moreover, none of the art provides any indication that the claimed PPI can be administered in a tablet oral dosage and successfully achieve an immediate release.

Further, the person of ordinary skill in the art would not have an apparent reason to combine the teachings of the cited prior art with each other. First, McCullough's teachings focus on compositions requiring the use of sucralfate. However, throughout the specification, Applicant explains that sucralfate is undesirable as the active ingredient. *See, e.g.*, 8:3-18, 15:19-

22, 22:27-31, 51:5-10. In fact, although McCullough attempts to make various combinations with various acid-related active ingredients, the cited portions of McCullough do not disclose using a tablet comprising non-enteric coated omeprazole and sodium bicarbonate in the ranges claimed together with a disintegrant wherein the tablet has low friability and a rapid disintegration time. There is no apparent teaching to employ acid-labile active agents with the embodiments alluded to in McCullough. Significantly, the Office Action fails to cite any apparent reason why one of skill in the art would apply the teachings of McCullough to Carroll, Whittle and Nomura to develop a non-enteric tablet formulation comprising about 10-40 mg of omeprazole, about 1 mEq to about 20 mEq of sodium bicarbonate and a disintegrant.

Likewise, Carroll and Whittle both fail to teach the use of a non-enteric coated proton pump inhibitor in a tablet dosage form, let alone non-enteric coated omeprazole with sodium bicarbonate in the claimed ranges. Nor does either reference disclose that the tablet containing omeprazole has low friability and a rapid disintegration time. Similarly, Nomura makes no disclosure of tablet formulations containing the claimed amounts of sodium bicarbonate and non-enteric coated omeprazole in a tablet. Nor does Nomura convey to the person of skill in the art the importance of low friability and a rapid disintegration time. Further, the office action cites nothing in Carroll, Whittle or Nomura that would suggest to the skilled artisan to combine their teachings with McCullough or with each other.

In addition, the Office dated November 10, 2011, states, "Applicant admits that omeprazole is a PPI and is available in micronized form." While any statements made by the Applicant in its own specification are not "prior art," Applicant disagrees that any such statements are admissions that the prior art renders the claimed invention obvious. The fact that the Examiner points to Applicant's own statements in an attempt to bolster its case suggests that the prior art is devoid of any apparent reason to combine their teachings to arrive at the claimed invention. Moreover, prior to Applicant's invention, one of skill in the art would not reasonably expect the claimed invention to be a successful invention.

Based on the foregoing reasons and amendments, a *prima facie* case of obviousness has not been established. Accordingly, amended claims 75, 77, 84-89 and 91 are not obvious over the cited references. Therefore, Applicant respectfully requests withdrawal of this rejection.

II. PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 75, 77, 84-89 and 91 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over various claims of co-pending Application Nos. 10/407,522 and 10/418,410. In addition, Claims 75, 77, 84-89 and 91 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over several claims of U.S. Patent Nos. 6,780,882, 6,699,885 and 7,399,772. Applicant will submit a terminal disclaimer once allowable subject matter is indicated.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that the claims as submitted by way of this amendment are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution. Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

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